JAN 1 3 2003

K023459

Premarket Notification 510(k) Summary
As required by section 807.92
Datex-Ohmeda S/5 Entropy Module, M-ENTROPY and Accessories

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

October 11, 2002

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Datex-Ohmeda S/5 Entropy Module, M-ENTROPY and Accessories

COMMON NAME:

EEG and FEMG Measurement Module with Entropy variables

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

GWQ	Electroencephalograph	882.1400
GXY	Electrode, cutaneous	882.1320

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda Entropy Module, M-ENTROPY and accessories is substantially equivalent in safety and effectiveness to the legally marketed predicate Datex-Ohmeda S/5™ BIS module M-BIS (K013389).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Datex-Ohmeda Entropy module, M-ENTROPY is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda Entropy module, M-ENTROPY can be used with the following Datex-Ohmeda modular monitors: S/5™ Anesthesia Monitor (AM) with main software L-ANE03(A)..00 or newer version, and S/5™ Compact Anesthesia Monitor (CAM) with main software L-CANE03(A)..00 or newer version. Entropy is an innovative monitoring modality which is designed to provide information on the electrical activity of the CNS during general anesthesia. Entropy monitoring is based on acquisition, and processing of raw EEG and FEMG signals by using the Entropy algorithm. The entropy algorithm is a Datex-Ohmeda application of spectral entropy based on information theory. The Datex-Ohmeda Entropy Module for the Datex-Ohmeda S/5™ Monitoring system may be used as an aid in monitoring the effects of certain anesthetic agents. The Datex-Ohmeda Entropy sensor is a rectangular shaped, pre-gelled array of three (3) Zipprep® electrodes that is applied to the patient's skin to record electrophysiological (such as EEG) signals. It is a low impedance, single patient use, disposable sensor that is designed for application to the frontal / temporal area. The Datex-Ohmeda Entropy sensor is designed to provide ease of use and electrode placement accuracy. The sensor is used in conjunction with M-ENTROPY. The Datex-Ohmeda Entropy sensor cable connects the Entropy sensor to the M-ENTROPY module both mechanically and electrically.

Calculated parameters are:

- Response Entropy, RE (range 0-100), continuous processed variable for fast detection of activation of facial muscles, i.e. FEMG.
- State Entropy, SE (range 0-91), continuous processed variable calculated from the EEG. SE is designed to be sensitive to the hypnotic effect of anesthetic drugs in the brain.
- Burst Suppression Ratio, BSR (range=0-100%), the percentage of epochs in the past 60 seconds in which the EEG signal is considered suppressed.

All the calculated parameters can be selected on the display, and trended. The raw EEG signal can be displayed from one of the two monitored channels. The waveform size, color and sweep speed can be adjusted. Alarms for Entropy are taken care of by the host monitor and follow the user interface for alarms in Datex-Ohmeda S/5 patient monitors. There are auditory and visual alarms and user adjustable limits for Entropy variables. The default is OFF, because the device does not provide information to be used for treatment or therapy.

INTENDED USE as required by 807.92(a)(5)

Intended use:

The Datex-Ohmeda Entropy module , M-ENTROPY and accessories are intended to be used with Datex-Ohmeda modular multiparameter monitors for monitoring the neurophysiological status of hospitalized patients.

Indications for use:

The Datex-Ohmeda Entropy Module is indicated for monitoring the state of the central nervous system (CNS) by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals in the anesthesia environment. The spectral entropies, State Entropy (SE) and Response Entropy (RE), are processed EEG and FEMG variables, and may be used as an aid in monitoring the effects of certain anesthetic agents. The Entropy module is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda Entropy module, M-ENTROPY is a single-width plug-in parameter module for a Datex-Ohmeda modular monitoring system. The Datex-Ohmeda Entropy module, M-ENTROPY can be used with the following Datex-Ohmeda modular monitors: S/5™ Anesthesia Monitor (AM) with main software L-ANE03(A)..00 or newer version, and S/5™ Compact Anesthesia Monitor (CAM) with main software L-CANE03(A)..00 or newer version. The predicate Datex-Ohmeda BIS module, M-BIS can be used with the following Datex-Ohmeda modular monitors: S/5 Anesthesia Monitor(AM), S/5 Compact Anesthesia Monitor (CAM), S/5 Critical Care Monitor (CCM) and S/5 Compact Critical Care Monitor (CCCM) with main software L-ANE02(A)..00 or L-ICU02(A)..00 or newer version. M-ENTROPY and the predicate M-BIS are modules that are used to calculate parameters from electroencephalograph (EEG) and frontal electromyograph (FEMG) signals. M-ENTROPY provides two spectral entropy parameters State Entropy (SE) and Response Entropy (RE). Whereas M-BIS provides Bispectral Index (BIS), Signal Quality Index (SQI), Suppression Ratio (SR) and Electromyography (EMG) variables . The sensors used for M-ENTROPY and M-BIS measurements are based on similar electrode technology. The sensor placement is similar, but the graphical printing is different. Mechanically M-ENTROPY and M-BIS modules are similar, but M-BIS has separate preamplifier (headbox), whereas M-ENTROPY has the preamplifier built-in to the module. The comparison above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda Entropy module M-ENTROPY.

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The Datex-Ohmeda Entropy Module, M-ENTROPY and accessories complies with the safety standards below and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance with the following mandatory and voluntary standards has been made:

- IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 (Part 1: General requirements for safety)
- EN 60601-1:1990+ A1:1993 + A13:1996 + A2:1995 (identical to IEC60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995)
- CAN/CSA C22.2 No. 601.1-M90 + S1:1994 (Canadian deviations to IEC 60601-1:1988 + Amdt. 1:1991) + S2:1998 (=IEC Amdt 2:1995)
- UL 2601-1, October 24, 1997 (U.S. deviations to IEC 60601-1:1988 + Amdt. 1:1991+ Amdt. 2:1995)
- AAMI ES1-1993 (Safe current limits for electromedical apparatus)
- Electroencephalograph Devices Guidance for 510(k) Draft Document Version 1.0 November 3, 1997
- IEC 601-2-26 Medical electrical equipment. Part 2: Particular requirements for the safety of electroencephalographs 04/01/94
- ISO 14971 Ed. 1: Medical devices - Application of risk management to medical devices
- FDA Performance standard, 21 CFR Part 898.12 - PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

Conclusion:

The summary above shows that there are no new questions of safety and effectiveness for the Datex-Ohmeda Entropy Module, M-ENTROPY and accessories as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 3 2003

Datex-Ohmeda
Joel Kent
Manager, Quality and Regulatory Affairs
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K023459
Trade/Device Name: Datex-Ohmeda S/5 Entropy Module, M-Entropy and Accessories
Regulation Number: 882.1400
Regulation Name: EEG and FEMG measurement device
Regulatory Class: Class II
Product Code: FYX
Dated: October 11, 2002
Received: October 15, 2002

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

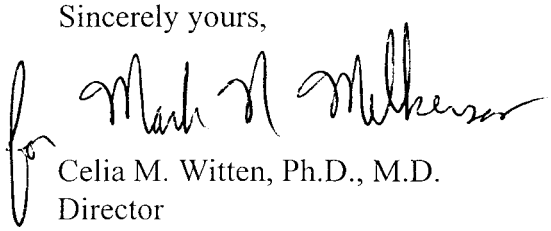
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023459

Device Name: Datex-Ohmeda S/5™ Entropy Module (M-ENTROPY) and accessories

The Datex-Ohmeda Entropy Module is indicated for monitoring the state of the central nervous system (CNS) by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals in the anesthesia environment. The spectral entropies, State Entropy (SE) and Response Entropy (RE), are processed EEG and FEMG variables, and may be used as an aid in monitoring the effects of certain anesthetic agents. The Entropy module is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023459